UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris

DECLARATION OF STEVE W. BERMAN IN SUPPORT OF PLAINTIFFS' RESPONSE TO THE TRACK TWO DEFENDANTS' SUBMISSION REGARDING THE MEANING OF AWP

I, Steve W. Berman, duly declare as follows:

1. I am a partner of Hagens Berman Sobol Shapiro LLP, resident in its Seattle, Washington, office, and I am co-lead counsel for the Plaintiffs in the above-captioned matter. I submit this declaration in support of Plaintiffs' Response to the Track 2 Defendants' Submission Regarding the Meaning of AWP.

2. Attached hereto are true and correct copies of the following exhibits:

Ex. A	*Medicare Program; Fee Schedule for Physicians' Services*, 56 Fed. Reg. 59525 (Nov. 25, 1991)
Ex. B	*Medicare Program; Fee Schedule for Physicians' Services*, 56 Fed. Reg. 25800 (June 5, 1991)
Ex. C	*New York v. Pharmacia, et al.*, RJI No. 01-03-076343 (N.Y. Sup. Ct. Albany County July 19, 2006)

I certify under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of August, 2006.

/s/ Steve W. Berman
STEVE W. BERMAN

CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **DECLARATION OF STEVE W. BERMAN IN SUPPORT OF PLAINTIFFS' RESPONSE TO THE TRACK TWO DEFENDANTS' SUBMISSION REGARDING THE MEANING OF AWP**, to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on August 21, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

By **/s/ Steve W. Berman**

Steve W. Berman
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Exhibit A

LEXSEE 56 FED. REG. 59525

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

AGENCY: Health Care Financing Administration (HCFA), HHS.

42 CFR Parts 405, 413, and 415

Medicare Program; Fee Schedule for Physicians' Services

[BPD-712-F]

RIN 0938-AE91

56 FR 59502

November 25, 1991 PART I OF XV

ACTION: Final rule.

SUMMARY: This final rule sets forth a fee schedule for payment for physicians' services beginning January 1, 1992. Establishment of this fee schedule is required by section 6102(a) of the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1990. This final rule explains which services will be included in the fee schedule and sets forth the formula for computing payment amounts. Application of transition rules during 1992 through 1995 is also described, as well as other adjustments to fee schedule payment amounts.

DATES: These regulations apply to services furnished beginning January 1, 1992. These regulations are effective January 1, 1992.

ADDRESSES: To order copies of the Federal Register containing this document, send your request to: U.S. Government Printing Office, Order and Information Desk, Washington, DC 20402-9329.

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Copies of this final rule on high density 3.5 inch personal computer diskettes can also be obtained from the Government Printing Office by requesting stock number 069-001-00038-6. The file formats on the diskettes are Word Perfect 5.0, Lotus 123 (version 2.01), and comma delimited ASCII files. The diskettes will be accompanied by the printed Federal Register document.

FOR FURTHER INFORMATION CONTACT: Terrence L. Kay, (410) 966-4494.

TEXT: SUPPLEMENTARY INFORMATION:

Overview

In this final rule, we explain in detail the statutory authority for the physician fee schedule and the regulations under that authority. Addenda to this rule provide technical documentation to the fee schedule tables, tables containing relative values for physician services and geographic practice cost index values, and information to assist readers in obtaining documents referenced in this final rule.

This final rule adds a new 42 CFR part 415 to apply to physicians' services furnished beginning on January 1, 1992. Existing rules pertaining to reasonable charge payment at 42 CFR part 405, subpart E are being amended to reflect the more limited application of reasonable charge principles once the physician fee schedule becomes effective.

The information in this final rule updates the information supplied June 5, 1991 in the proposed rule *(56 FR 25792)*. Elsewhere in the preamble of this final rule, we have summarized and responded to the comments received in response to the proposed rule and the proposed notice concerning "National Standardization of 'Global Surgery' Policy" that was published in the Federal Register on January 8, 1991 *(56 FR 699)*.

To assist readers in referencing sections contained in this final rule, we are providing the following table of contents:

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In addition, because of the many agencies and terms to which we refer by acronym in this final rule, we are listing those acronyms and their corresponding terms in alphabetical order below:

AAO -- American Academy of Ophthalmology

ACR -- American College of Radiology

AFROC -- Association of Freestanding Radiation Oncology Centers

AHPB -- Adjusted historical payment basis

AMA -- American Medical Association

APA -- Administrative Procedure Act

ASA -- American Society of Anesthesiology

ASC -- Ambulatory surgical center

AWP -- Average wholesale price

BMAD -- [Part] B Medicare Annual Data

CAP -- College of American Pathologists

CAT -- Computerized axial tomography

CBO -- Congressional Budget Office

CF -- Conversion factor

CFR -- Code of Federal Regulations

CHER -- Center for Health Economics Research

CMD -- Carrier medical director

CNS -- Clinical nurse specialist

CP -- Clinical psychologist

CPR -- Customary, prevailing, and reasonable

CPT -- Current Procedural Terminology, 4th Edition (copyrighted by the American Medical Association)

CRNA -- Certified registered nurse anesthetist

CRVS -- California Relative Value Studies

CSW -- Clinical social worker

CWF -- Common working file

CY -- Calendar year

DHHS -- Department of Health and Human Services

DME -- Durable medical equipment

DO -- Doctor of Osteopathy

DRG -- Diagnosis-related group

EKG -- Electrocardiogram

EO -- Executive Order

ERCP -- Endoscopic retrograde cholangiopancreatography

ESWL -- Extracorporeal Shock Wave Lithotripsy

FDA -- Food and Drug Administration

FTE -- Full-time equivalent

FY -- Fiscal year

GAF -- Geographic adjustment factor

GPCI -- Geographic practice cost index

HHA -- Home health agency

HCFA -- Health Care Financing Administration

HCPCS -- HCFA Common Procedure Coding System

HHS -- Department of Health and Human Services

HPSA -- Health Professional Shortage Area

HUD -- Department of Housing and Urban Development

IIC -- Inflation-indexed charge

JAMA -- Journal of the American Medical Association

LOCM -- Low osmolar contrast media

LPN -- Licensed practical nurse

MAAC -- Maximum Allowable Actual Charge

MAC -- Monitored Anesthesia Care

MCM -- Medicare Carriers Manual

MCP -- Monthly Capitation Payment

MD -- Doctor of Medicine

MEI -- Medicare Economic Index

MP -- Multiple patients

MRI -- Magnetic resonance imaging

MSA -- Metropolitan statistical area

MVPS -- Medicare volume performance standards

NAMCS -- National Ambulatory Medical Care Survey

NCH -- National Claims History

NF -- Nursing facility

NM -- Nurse-midwife

NP -- Nurse practitioner

OBRA -- Omnibus Budget Reconciliation Act

OIG -- Office of the Inspector General

OMB -- Office of Management and Budget

OT -- Occupational therapist

PA -- Physician assistant

Ph.D -- Doctor of philosophy

PHS -- Public Health Service

Pub. L. -- Public Law

PPRC -- Physician Payment Review Commission

PPS -- Prospective payment system

PRMS -- Puerto Rico Medical Society

PRO -- [Utilization and Quality Control] Peer Review Organization

PT -- Physical therapist

RFA -- Regulatory Flexibility Act

RN -- Registered nurse

RVS -- Relative value scale

RVU -- Relative value unit

S&I -- Supervision and interpretation (relates to coding of radiological services)

SCVIR -- Society of Cardiovascular and Interventional Radiology

SMI -- Supplementary Medical Insurance

SP -- Single patient

SPECT -- Single photon emission computed tomography

TEFRA -- Tax Equity and Fiscal Responsibility Act of 1982

UI -- Urban Institute

UIP -- University of Iowa Physicians

I. Background

A. Legislative History

The Medicare program was established in 1965 by the addition of title XVIII to the Social Security Act (the Act). The Social Security Amendments of 1965 created two insurance programs: Medicare Part A or Hospital Insurance and Medicare Part B or Supplementary Medical Insurance. These original statutory provisions established the principles of reasonable charge payment for physicians' services and certain other services under Part B. The key provisions governing the reasonable charge payment methodology are set forth in sections 1833 and 1842(b) of the Act and in 42 CFR part 405, subpart E. While statutory amendments have moved certain Part B services such as radiologists' services, durable medical equipment (DME), and clinical laboratory services from reasonable charge payment to a fee schedule, physicians' services have generally been paid based on reasonable charge principles throughout the first 25 years of the program's operation.

In general, the reasonable charge for a physician's service is the lowest of: (1) The physician's actual charge, (2) the physician's customary charge, or (3) the prevailing charge in the locality for similar services. The customary charge is the median charge of the physician for the service during the July through June data collection period preceding the current calendar year (CY). These charges are arrayed in ascending order and the median or midpoint of the charge data is selected as the customary charge. The prevailing charge limit for a particular service in a locality is an amount set high enough to cover the full customary charges of the physicians whose billings have accounted

for at least 75 percent (that is, the 75th percentile) of the charges in the locality for that service. Since 1975, changes in prevailing charge limits from year to year have been constrained by statute to the amount of inflation in medical costs as measured by the Medicare Economic Index (MEI).

A major change in the Medicare physician payment rules was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Public Law 101-239) on December 19, 1989. Section 6102 of Public Law 101-239 amended title XVIII of the Act by adding a new section 1848, "Payment for Physicians' Services". The new section contains three major elements: (1) Establishment of volume performance standard rates of increase for physician services' expenditures; (2) replacement of the reasonable charge payment mechanism with a fee schedule for physicians' services; and (3) replacement of the maximum actual allowable charge (MAAC), which constrains the total amounts that nonparticipating physicians can charge Medicare beneficiaries for covered services, with a new limiting charge.

On November 5, 1990, Congress enacted Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990, which contained several modifications and clarifications to the Public Law 101-239 provisions establishing the physician fee schedule. These modifications have been taken into account throughout this final rule. Public Law 101-508 also made a number of revisions to physician payment amounts for 1991, which will affect payment amounts under the fee schedule, given the budget neutrality requirement for 1992 and the transition rules. (Budget neutrality is explained more fully in the discussion of the conversion factor (CF).)

This final rule is being issued in accordance with section 1848(b)(1) of the Act, as added by section 6102 of Public Law 101-239, which requires that: "Before January 1 of each year beginning with 1992, the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas * * * for the year." Section 1848 requires that the fee schedule include national uniform relative values for all physicians' services. The relative value of each service must be the sum of relative value units (RVUs) representing physician work, practice expenses net of malpractice expenses, and the cost of professional liability insurance (malpractice insurance). Nationally uniform relative values must be adjusted for each locality by a geographic adjustment factor (GAF). (Only one-fourth of the physician work relative value is subject to adjustment.) The CF (converting total RVUs into dollar payment amounts) must be budget neutral, so that had the fee schedule been applied during 1991 it would have resulted in the same level of aggregate payments as would be made under the reasonable charge system. The new fee schedule must be phased in over 4 years, beginning in 1992, with the new rules fully effective in 1996. During 1992 through 1995, transition provisions generally blend the old payment amounts with the new. In addition, this final rule sets forth a limit on amounts that nonparticipating physicians can charge beneficiaries under section 1848(g) of the Act. This new limit is called the limiting charge. The limit went into effect, as required by law, on January 1, 1991. Section 5302 of the Medicare Carriers Manual (MCM) explains the limiting charge.

B. Development of the Fee Schedule

Development of the concepts and methodology underlying the physician fee schedule has been under way for a number of years. Based on Congressional mandates contained in Public Law 99-272 (Consolidated Omnibus Budget Reconciliation Act of 1985), Public Law 99-509 (OBRA of 1986), and Public Law 100-203 (OBRA of 1987), we began our effort to develop a physician fee schedule based on a relative value scale (RVS). We were assisted in this task by a number of ex-

c. *Nurse practitioners (NPs) and clinical nurse specialists (CNSs).* The law limits allowed charges for services of NPs furnished in NFs covered under section 1861(s)(2)(k)(ii) of the Act to 85 percent of the physician fee schedule amount. For services of NPs and CNSs covered under section 1861(s)(2)(k)(iii) furnished in rural areas as defined for the hospital prospective payment system (PPS), the allowed amount will be limited to the lower of the actual charge or 75 percent of the physician fee schedule amount for services furnished in a hospital; and 85 percent of the physician fee schedule amount in all other settings (§ 415.54).

d. *Certified registered nurse anesthetists (CRNAs).* We will use the same RVS for determining payment for both physician anesthesia services and CRNA services (§ 415.58). For a specific anesthesia code, the RVUs for the CRNA service will be the same as the RVUs for an anesthesia service personally performed by the anesthesiologist. The CF for a non-medically directed CRNA will be limited to the anesthesia CF applicable in that locality. We will not apply a limit on the CF for services of medically directed CRNAs.

e. *Nurse-midwives (NMs).* Payment for NMs will be limited to 65 percent of the physician fee schedule amount (§ 415.52).

f. *Clinical psychologists (CPs).* Diagnostic tests furnished by CPs will be paid under the physician fee schedule like all other fee schedule services. (Therapeutic and other diagnostic services of CPs will be paid under a separate rule, which is still being developed.)

g. *Clinical social workers (CSWs).* Covered diagnostic tests furnished by CSWs will be paid under the physician fee schedule like all other fee schedule services (§ 415.60) (Psychological testing services, however, are covered only if furnished by physicians or qualified psychologists). Therapeutic and other diagnostic services of CSWs will be limited to 75 percent of the fee schedule for CPs.

4. Provider-Based and Teaching Physicians

Direct patient care services of provider-based physicians, including those in teaching hospitals, with the exception of those under the cost election provision, will be paid under the physician fee schedule on the same basis as other physician services. The attending physician criteria (§ 405.521) for teaching physicians will remain in effect under the physician fee schedule.

5. Payment for Supplies, Services, and Drugs Furnished Incident to a Physician's Service

a. *Supplies.* Office medical supplies, except for drugs and certain supplies associated with performing the procedures listed in Addendum G of this final rule, will be considered to be practice expenses to the physician and payment will be included in the practice expense portion of the payment for a medical or surgical service to which they are incidental (§ 415.34(a)).

For procedures in Addendum G, we have established a practice expense RVU of 1.0 for supplies that are used incident to a physician's service but generally are not the type of routine supplies that are included in the practice expense RVU for specific physicians' services. We will pay, however, a separate allowance based on an RVU of 1.0 only if these supplies are billed (using procedure code A4550) in conjunction with procedures listed in Addendum G, and these procedures are performed in physicians' offices. The GPCI will not be applied to determine payment for supplies.

b. *Services.* Services of a nonphysician that are covered incident to a physician's service will be paid under the fee schedule as if the physician had furnished the services (§ 415.34(b)).

c. *Drugs.* We will use a standard method to pay for drugs (§ 405.517). We will base payment for a drug on the lower of the estimated acquisition cost or the national average wholesale price of the drug. If a drug has multiple sources, the median of the average national wholesale generic prices will be used. Estimated acquisition costs will be determined based on surveys of actual invoice prices paid by the providers furnishing the drug. In calculating estimated acquisition costs, indirect costs such as inventory, waste, and spoilage may be considered.

We are clarifying in § 405.517 that the payment policy for drugs applies to all drugs furnished to Medicare beneficiaries that are not paid on a cost or prospective payment basis. This includes drugs furnished by independent ESRD facilities. Accordingly, we are adding a new paragraph (c)(7) to § 413.170 that describes the payment rules for drugs furnished by ESRD facilities.

B. Formula for Computing Payment Amounts

Section 1848(a) of the Act specifies that payment for Medicare physicians' services must be based on the lesser of the actual charge or the payment amount computed under the fee schedule. Although the law refers to the fee schedule values as "payment amounts", in fact under the statutory formula the amount paid directly to a physician or beneficiary by Medicare will be 80 percent of the actual charge or 80 percent of the fee schedule payment amount, whichever is less. The beneficiary is required to pay the remaining 20 percent. (Throughout this final rule, we have used the terms "fee schedule payment amount," "payment amount," "payment," and "allowed charge" as used in the statute to include the amounts for which both the beneficiary and Medicare are responsible.)

Under the formula set forth in section 1848(b)(1) of the Act, payment amounts for particular services under the physician fee schedule will be computed as the product of three factors: (1) A relative value for the service, (2) the GAF for the fee schedule area, and (3) a nationally uniform dollar CF. (Although we generally describe a single nationally uniform CF, different CFs for surgical services and other services may be established as part of the Medicare volume performance standards (MVPS) and annual update process. A discussion of the update process appears in the section on the CF.) This general formula can be expressed as:

Payments=RVUt S X GAFt SA X CF

where

RVUt=Total relative value units for the service

GAFt=Total geographic adjustment factor for the fee schedule area

CF=Uniform national CF

S =Service

A =Fee schedule area

physicians to patients in provider settings may be made directly to the provider on the basis of a single per diem rate if the provider has a uniform all-inclusive rate for services to patients. This method is mainly used by government hospitals.

Response: Section 1848(a)(1) of the Act states that physicians' services currently paid on a reasonable charge basis must be paid under the fee schedule beginning in 1992. The per diem method, except when used in a qualified teaching facility under the cost election, is a method of calculating reasonable charges and is authorized under the reasonable charge sections of current law and regulations. We therefore believe we are required to make payment based on the fee schedule and not on this method of reasonable charge billing. Although we recognize that converting to itemized billing will require some effort and expense, many conversions have been done in the past. Further, with existing computer billing services the effects of this conversion should be minimal. Also, we do not believe it is unreasonable for an entity paid under the fee schedule for physicians' services to identify the services for which payment is being requested.

4. Payment for Supplies, Services, and Drugs Furnished Incident to a Physician's Service

a. *Supplies.* Under the proposed rule (§ 415.32(a)), office medical supplies, except for drugs and specified supplies, would be considered to be practice expenses to the physician, and payment would be included in the practice expense portion of the payment for the medical or surgical services to which they were incidental.

We proposed to establish a separate fee schedule allowance for the following expensive supplies: Lumbar puncture trays, thoracentesis trays, cystoscopy trays, surgical trays, catheter insertion trays, bone marrow aspiration trays, and venous access catheters. We requested comment on this approach that could be of assistance in establishing payment amounts for these items.

[Separate Payment for Medical Supplies]

Comment: Some commenters stated that bundling payment for supplies into the service would result in inadequate payment for the supplies when they are used and improper increases in payment for services that use no supplies because the amount and cost of supplies used for different services varies so much. Some commenters stated that bundling payment into the service would result in physicians requiring the patient to buy the supplies and bring them to the office when the service is furnished.

Some commenters stated that carriers should have the discretion to pay for additional supplies. Some commenters suggested that we develop specific criteria for determining whether a supply should be subject to a separate fee schedule allowance. According to these commenters, if the supply cost represents a disproportionate share of the RVU, the supply should be separately payable. Other commenters recommended that we expand the list of supplies to include reusable trays that include highly specialized instruments "which are far beyond the supplies incident to practice." Some commenters listed specific supplies that they believe should be separately payable. Other commenters expressed support for our proposal but urged us to base payment on accurate cost data. Commenters believe, however, that implementation of this policy should not be delayed in the event we do not have sufficient data to determine a national payment. These commenters prefer that we implement this policy and make adjustments in the fee schedule amounts as better data become available.

-- Services that are ancillary to the work of the physician and do not require the advanced training and skill of a physician or a nonphysician practitioner, but which can be and are typically performed by a registered nurse (RN), licensed practical nurse (LPN), or health assistant (for example, injections and dressing changes that can be performed by an RN or LPN).

The commenters stated that nonphysician practitioners who substitute for physicians should be paid the same amount as physicians for the services they furnish regardless of whether the service is "incident to" a physician's service or under the nonphysician practitioner coverage provisions, but that when a nonphysician employee of a physician furnishes an ancillary service that does not require the skills of a physician, the payment to the physician should not include the physician work portion of the payment.

Some commenters supported the proposed use of a modifier to identify services furnished by a nonphysician practitioner or nonphysician, but covered as "incident to" a physician service. Other commenters opposed the proposed use of a modifier to identify services furnished by a nonphysician incident to a physician's service when the physician has no contact with the patient. They indicated that this requirement would lead to confusion, paperwork burden, and would invite circumvention, such as a physician stopping by to ask how the patient is feeling.

Response: While we respect the arguments made in regard to this issue, we intend to continue our longstanding policy on "incident to" services as part of the physician fee schedule for the time being. At this time, we have no data on which "incident to" services are being furnished, the frequency of these services, or who is performing them. We believe this information would be essential in order to establish criteria. Moreover, if we established these criteria, we would be concerned whether the statutory methodology for calculating practice expense and malpractice expense would result in appropriate payment for the resources invested in the nonphysician staff who are furnishing these services. We believe this issue of "incident to" services needs to be carefully considered within the context of payment for practice expenses. In addition, at this time we have decided not to require the use of a modifier to indicate that the physician is billing for a service furnished by a nonphysician practitioner or other nonphysician without a physician encounter. We will continue to consider this issue and may selectively test the use of a modifier to determine to what extent physicians bill for services totally furnished by nonphysician employees under the "incident to" provision.

[Physical Presence of a Physician]

Comment: Commenters objected to the current requirement that the physician be physically on the premises in order for the services of a nonphysician employee to be billed as "incident to" a physician's service.

Response: This requirement is a longstanding coverage requirement for which no change was proposed in the proposed rule and for which no change has been made in this final rule.

c. *Drugs and injections.* We proposed to use a standard method to pay for drugs (§ 415.34). We proposed to base payment for drugs on 85 percent of the national average wholesale price of the drug. For high volume drugs, we proposed that payment be limited to the lower of the estimated actual acquisition costs as determined by us and specified in instructions to carriers, or 85 percent of the national average wholesale price (AWP) of the drug.

When a physician provides a visit or other service to a beneficiary and, during the encounter, the beneficiary receives an injection, we proposed no additional payment would be made for the injection. The drug would be paid separately as discussed above.

Under the proposed rule, in unusual circumstances if no evaluation and management service is furnished and the physician bills for the injection, payment for the injection would be based on the RVUs for the applicable injection code.

We proposed to pay separately for chemotherapy infusions and chemotherapy administration into specialized body cavities.

[Payment for Drugs]

Comment: We received a great many comments on this issue, primarily from oncologists indicating that our 85 percent standard was inappropriate. The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP -- particularly multisource drugs -- while others were not discounted. Other commenters suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not. The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs.

Also, a number of comments from the oncologists indicated that we should use an add-on to cover the cost of breakage, wastage, shelf-life limitations, and inventory costs associated with chemotherapy agents. Some commenters also suggested that this add-on payment was needed to account for shortfalls in chemotherapy administration payments. Without adequate compensation, commenters suggested, many physicians would perform the service in hospital outpatient departments at substantially higher costs. Also, some commenters suggested that physicians would refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case, the drugs would not be covered by Medicare since the physician did not incur any costs for the drugs.

Response: After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians, or other providers as appropriate, actually pay for the drugs. Carriers could survey a sample of the physicians who furnish the drugs to obtain cost information. As an alternative, carriers could request that physicians periodically provide cost information when they submit claims for payment for the drugs. For certain types of drugs, such as chemotherapy drugs, there may be significant indirect costs such as inventory costs, waste, and spoilage. Carriers may consider these costs, if documented, as part of the acquisition cost of a drug.

For high volume or high cost drugs as determined on a national basis, we may designate certain carriers, which represent different geographic areas of the country, to survey physicians in their area to determine the average cost of the drugs. We will distribute the results of these surveys to all carriers. Carriers will be free to evaluate the results of the surveys and use this information in conjunction with any information they have obtained locally to determine the payment for the drugs in their

service areas. The revised payment policy for drugs appears in § § 405.517 and 415.36 of the final regulations.

[Antigens as Drugs]

Comment: Commenters objected to our considering antigens to be drugs or biologicals, and therefore asked that they be excluded from the fee schedule and paid on a reasonable charge basis. They stated that antigens are covered under section 1861(s)(2)(G) of the Act. Also, they noted that that section of the Act is not identified in the definition of "physicians' services" for fee schedule purposes set forth in section 1848(j)(3) of the Act.

Response: After considering the comment, we agree with the commenters. Thus, we are excluding antigens prepared by one physician for administration by another from the physician fee schedule (CPT codes 95135 through 95170). Carriers will continue to pay for these antigens under the current payment methodology.

[Payment for Injection Administration]

Comment: Commenters objected to the proposed policy for drugs and the related bundling of payment for administration of injections into other medical services furnished at the same encounter as presenting a "double hit". They stated that not only would the physician be paid less than his/her cost for the drug, but also, there would be no payment for the additional service of the injection furnished to the patient. They stated that this approach is inconsistent with payment based on resource costs.

Response: As we indicated in our discussion of payment for drugs, we have revised our proposed payment policy for drugs. With respect to payment for injections, we have decided to pay separately for cancer chemotherapy injections, including intra-muscular, intravenous, intra-arterial, and subcutaneous injections, in addition to the visit furnished on the same day. Commenters made a convincing case that these cancer chemotherapy injections are more complex than other injections incident to a physician's service. Therefore, we will pay for all injection procedures in the CPT range of 96400 through 96549 separately in addition to any visit service furnished. For further information on how to bill for the visit, see the discussion on modifiers that appears in this section of the preamble.

We were not convinced by commenters, however, that other intra-muscular, intravenous, intra-arterial, and subcutaneous injections are sufficiently complex that separate payment should be made for them. Therefore, payment for CPT codes 90782 through 90784 will be included in payment for visits or other procedures that are furnished on the same day.

[Payment for ESRD Drugs]

Comment: Several commenters objected to applying the proposed 85 percent of AWP allowance for drugs to ESRD facilities. They stated that their costs for drugs used to treat ESRD patients are greater than this due to several factors.

Response: We are accepting the commenters' suggestions not to apply the proposed 15 percent reduction of the currently allowed AWP for drugs and to consider their invoice costs in determining allowances for ESRD drugs. Therefore, the new payment allowance will be the lower of the facility's estimated acquisition cost of the drug (for example, as determined by the invoice) or the national AWP of the drug. The program's payment will be subject to the usual Medicare Part B deductible and coinsurance requirements.

LEXSEE 56 FR 59525

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

AGENCY: Health Care Financing Administration (HCFA), HHS.

42 CFR Parts 405, 413, and 415

Medicare Program; Fee Schedule for Physicians' Services

[BPD-712-F]

RIN 0938-AE91

56 FR 59502

November 25, 1991 PART II OF XV

ACTION: Final rule.

TEXT: [Practice Costs Methology]

Comment: Some commenters noted specific problems with the proposed practice costs methodology. According to these commenters, Harvard raised three specific comments. First, practice costs vary by specialty but data were gathered for an insufficient number of specialties. Second, the specialty-specific cost data were not evaluated or adequately validated. Third, the charge-based practice cost measurement does not adequately allocate practice costs between fixed and variable expenses.

Response: Section 1848 of the Act requires us to determine the average percentage allocation of resources among the work component, the practice expense component, and the malpractice expense component. These percentages must be based on national data that describe the elements of physician practice costs and revenues by physician specialty.

Given this statutory requirement, we used the best available data to determine practice expense percentages. We believe the practice expense data we used from the AMA's Socioeconomic Monitoring Report are the best available for the following reasons:

-- The survey is the comprehensive single source of data on physician practice expenses.

-- The survey is representative of physicians both geographically and across specialties.

-- The survey is performed annually, includes a random sample of physicians each year, and with some minor exceptions, provides consistent data.

-- The survey solicits information using a consistent set of questions for all specialties.

cent. When the fee schedule is fully effective, Mississippi is predicted to be the State experiencing the largest increases in payments overall as a result of the fee schedule. In that State, payments per service will be 12 percent higher than they would have been under a continuation of the CPR payment rules and payments overall will be 14 percent higher. Among States experiencing the largest reductions relative to the CPR system will be Alaska and Nevada. In the first transition year, physicians in Alaska can expect a 10 percent reduction in payments per service and a 2 percent reduction in payments overall. When the fee schedule is fully effective in 1996, physicians in Nevada can expect a 20 percent reduction in payments per service and a 6 percent reduction in payments overall, relative to a continuation of CPR payments. Like specialty level effects, these State level effects are generally consistent with those shown in earlier analyses.

There will also be redistributions of payments within States. Changes in payment levels could vary more widely if we compared smaller geographic areas than States, such as fee schedule areas. Variation at the fee schedule area level could be greater than at the State level, since the effects within States tend to offset one another. (For example, many States contain both urban and rural areas. Increases in rural areas may be offset by decreases in urban areas.)

e. *Effects of separate payment for drugs.* We have estimated the budgetary effects of our final policy for separate payment for certain drugs. As explained in the preamble section on drug payment rules, carriers generally base payment for covered drugs on the physician's estimated cost of the drug using one of the wholesale price guides such as the Red Book, which is an annual pharmacists' reference published by the Medical Economics Company, Inc., Oradell, New Jersey. Under our final policy, carriers will be instructed to base payment for drugs on the lower of the estimated acquisition cost or the national average wholesale price of the drug as published in the Red Book and similar price listings. Our policy will therefore reduce payments for drugs by approximately $5 million in FY 1992, $15 million in FY 1993, $15 million in FY 1994, $20 million in FY 1995, and $20 million in FY 1996.

2. Effects on Beneficiaries' Costs and Access to Services

Medicare beneficiaries incur out-of-pocket expenses in relation to their Medicare-covered services arising from (1) the monthly Part B premium ($31.80 in 1992, up from $29.90 in 1991), (2) the annual deductible (increased from $75 in 1990 to $100 in 1991), (3) the 20 percent coinsurance, and (4) balance billing (that is, billing the beneficiary for an amount in excess of the Medicare allowed charge if the claim is not assigned). The implementation of the Medicare physician fee schedule and the limiting charge on balance billing as required by law and set forth in this final rule will have important effects on the amounts of beneficiary coinsurance and the amounts of balance billing permitted.

Concern about rising beneficiary out-of-pocket costs has led to an increasing emphasis over the past several years in encouraging physicians' Medicare participation (which requires accepting assignment for all cases), in increasing assignment rates, and limiting the amounts of balance billing. In fact, since Public Law 98-369 (the Deficit Reduction Act of 1984) established the participating physician program with its differential payment rates for participating and nonparticipating physicians, enrollment in the Medicare participating physician program has increased to 44.1 percent (April 1990 figure). Creation of the MAAC limits on balance billing (enacted as part of Public Law 99-509) gave physicians an additional incentive to participate. Participating physician charges represented approximately 72 percent of Medicare physician covered charges from April through June 1991. At the same time, assignment rates have also increased steadily so that from April through

Exhibit B

LEXSEE 56 FR 25800

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

AGENCY: Health Care Financing Administration (HCFA), HHS.

42 CFR Parts 405 and 415

Medicare Program; Fee Schedule for Physicians' Services

[BPD-2-P]

RIN 0938-AE91

56 FR 25792

June 5, 1991

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth a fee schedule for payment for physicians' services beginning January 1, 1992. Establishment of this fee schedule is required by section 6102(a) of the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1990. This proposed rule explains which services would be included in the fee schedule and sets forth the formula for computing payment amounts. Application of transition rules during 1992 through 1995 is also described, as well as other adjustments to fee schedule payment amounts.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 5, 1991.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-712-P, P.O. Box 26686, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-712-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

If you wish to submit comments on the information collection requirements contained in this proposed rule, you may submit comments to: Allison Herron, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the Federal Register containing this document, send your request to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 275-6802. The cost for each copy (in paper or microfiche form) is $1.50. In addition, you may view and photocopy the Federal Register document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register. The order desk operator will be able to tell you the location of the Government Depository Library nearest to you.
FOR FURTHER INFORMATION CONTACT: Terrence L. Kay, (301) 966-4494.

TEXT: SUPPLEMENTARY INFORMATION:

Overview

In this proposed rule, we explain in detail the statutory authority for the physician fee schedule and the provisions of the regulations we propose under that authority. Addenda to the rule provide technical documentation to the fee schedule tables, tables containing proposed relative values for physician services and geographic practice cost index values, and information to assist readers in obtaining documents referenced in the proposed rule.

This proposed rule would add a new 42 CFR part 415 to apply to physicians' services furnished beginning on January 1, 1992. Existing rules pertaining to reasonable charge payment at 42 CFR part 405 subpart E would be amended to reflect the narrower application of reasonable charge principles once the physician fee schedule becomes effective.

The information in this proposed rule updates the information supplied September 4, 1990 in the model fee schedule notice *(55 FR 36178).* Comments on the model fee schedule have been considered in developing the policies proposed here. (If commenters wish to have their comments summarized and responded to in the Federal Register, they should comment on this proposed rule and we will respond to them in the final rule.)

To assist readers in referencing sections contained in this proposed rule, we are providing the following table of contents:

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4. RVUs for Limited Licensed Practitioner Services

5. Radiology Services

a. Integration of Existing Radiologist Fee Schedule into Physician Fee Schedule

b. Rescaling Values for the Physician Fee Schedule

c. Portable X-ray

d. Other Radiology Issues

6. Anesthesia Services

a. Integration of Anesthesia Services into the Physician Fee Schedule

b. Elimination or Continuation of Recognition of Time Units

c. Method for Integrating Anesthesia Services

d. Payment for Specialized Services Furnished by Anesthesiologists

e. Monitored Anesthesia Care

f. Other Anesthesia Issues

7. Physician Pathology Services

8. Charge-based Computation of Practice Expense and Malpractice RVUs

9. Combining Work, Practice Expense, and Malpractice RVUs onto a Common Scale

10. Periodic Review and Adjustments in RVUs

a. Proposed Policy for Review and Adjustments

b. Establishment of Interim RVUs for New or Revised Services

c. Options for Establishing and Revising RVUs for Existing, Revised, and New Services

d. Creation and Review of RVUs for New or Revised Services

e. Implementation of the $20 Million Limitation

D. Geographic Adjustment Factors (GAFs)

E. Conversion Factor (CF)

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2. Accounting for Transition Payment Rules in CF Calculation

3. Determining the Initial CF

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B. Professional/Technical Component Services

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2. Diagnostic Tests

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3. Physician Pathology Services

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2. Bilateral Surgery (CPT modifier 50)

3. Providers Furnishing Less Than the Global Fee Package (CPT modifiers 54, 55, and 56)

4. Physicians Who Assist at Surgery (CPT modifiers 80, 81, and 82)

5. Two Surgeons and Surgical Team (CPT modifiers 62 and 66)

6. Unusual Services (CPT modifier 22) or Reduced Services (CPT modifier 52)

7. Multiple Modifiers (CPT modifier 99)

8. Multiple Patients and Single Patient Modifiers on Nursing Home Visit Bills (HCPCS alpha-numeric modifiers MP and SP)

9. Modifiers That Would Not Affect Payment Levels

a. CPT Modifiers That Would Not Affect Payment

b. HCPCS Alpha-numeric Modifiers That Would Not Affect Fee Schedule Payment Amounts

c. Carrier Unique Local Modifiers (HCPCS Level 3 modifiers beginning with the letters w through z)

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D. New Physician/Practitioner Adjustment

1. General and to Whom It Applies

2. Exceptions

3. Amounts of Adjustments

4. Years of Practice

E. Participating Physician Differential

F. Health Manpower Shortage Area Bonus Payment

In addition, because of the many agencies and terms to which we refer by acronym in this proposed rule, we are listing those acronyms and their corresponding terms in alphabetical order below:

AA -- Anesthetist assistant

ACR -- American College of Radiology

ACS -- American College of Surgeons

AMA -- American Medical Association

ASC -- Ambulatory surgical center

BMAD -- [Part] B Medicare Annual Data

CAT -- Computerized axial tomography

CBO -- Congressional Budget Office

CF -- Conversion factor

CFR -- Code of Federal Regulations

CHER -- Center for Health Economics Research

CNIBM Laser -- CoverageHPLAIID.PRSIition (copyrighted by the American Medical Association (1991))

CRNA -- Certified registered nurse anesthetist

CSW -- Clinical social worker

CWF -- Common working file

CY -- Calendar year

DHHS -- Department of Health and Human Services

DME -- Durable medical equipment

DO -- Doctor of Osteopathy

DRG -- Diagnosis-related group

EEG -- Electroencephalogram

EKG -- Electrocardiogram

EO -- Executive Order

FY -- Fiscal year

GAF -- Geographic adjustment factor

GPCI -- Geographic practice cost index

HHA -- Home health agency

HCFA -- Health Care Financing Administration

HCPCS -- HCFA Common Procedure Coding System

HHS -- Department of Health and Human Services

HI -- Hospital Insurance (Part A of the Medicare Program)

HMO -- Health maintenance organization

HMSA -- Health Manpower Shortage Area

ICF -- Intermediate care facility

ID -- Identification

IIC -- Inflation-indexed charge

MAAC -- Maximum Allowable Actual Charge

MAC -- Monitored Anesthesia Care

MCP -- Monthly Capitation Payment

MD -- Doctor of Medicine

MEI -- Medicare Economic Index

MP -- Multiple patient

MRI -- Magnetic resonance imaging

MSA -- Metropolitan statistical area

MVPS -- Medicare volume performance standards

NAMCS -- National Ambulatory Medical Care Survey

NCH -- National Claims History

NCHS -- National Center for Health Statistics

NF -- Nursing facility

NM -- Nurse midwife

NP -- Nurse practitioner

OBRA -- Omnibus Budget Reconciliation Act

OIG -- Office of the Inspector General

OMB -- Office of Management and Budget

OT -- Occupational therapist

PA -- Physician assistant

PBP -- Provider-based physician

PET -- Provider Education and Training

PHS -- Public Health Service

Pub. L. -- Public Law

PPRC -- Physician Payment Review Commission

PPR -- Physician Payment Reform

PROs -- [Utilization and Quality Control] Peer Review Organizations

PT -- Physical therapist

RFA -- Regulatory Flexibility Act

RVU -- Relative value unit

S&I -- Supervision and interpretation (relates to coding of radiological services)

SMI -- Supplementary Medical Insurance (Part B of the Medicare Program)

SNF -- Skilled nursing facility

SP -- Single patient

TEFRA -- Tax Equity and Fiscal Responsibility Act of 1982

UI -- Urban Institute

Background

I. Legislative History

The Medicare program was established in 1965 by the addition of title XVIII to the Social Security Act (the Act). The Social Security Amendments of 1965 created two insurance programs:

Medicare Part A or Hospital Insurance and Medicare Part B or Supplementary Medical Insurance. These original statutory provisions established the principles of reasonable charge payment for physicians' services and certain other services under part B. The key provisions governing the reasonable charge payment methodology are set forth in sections 1833 and 1842(b) of the Act and in 42 CFR part 405, subpart E. While statutory amendments have moved certain part B services such as radiologists' services, durable medical equipment (DME) and clinical laboratory services from reasonable charge payment to a fee schedule, physicians' services have generally been paid based on reasonable charge principles throughout the first 25 years of the program's operation.

In general, the reasonable charge for a physician's service is the lowest of (1) the physician's actual charge, (2) the physician's customary charge, or (3) the prevailing charge in the locality for similar services. The customary charge is the median charge of the physician for the service during the July through June data collection period preceding the current calendar year. These charges are arrayed in ascending order and the median or midpoint of the charge data is selected as the customary charge. The prevailing charge limit for a particular service in a locality is an amount set high enough to cover the full customary charges of the physicians whose billings have accounted for at least 75 percent of the charges in the locality for that service. Since 1975, changes in prevailing charge limits from year to year have been constrained by statute to the amount of inflation in medical costs as measured by the Medicare Economic Index (MEI).

A major change in Medicare physician payment rules was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101-239) on December 19, 1989. Section 6102 of Pub. L. 101-239 amended title XVIII of the Act by adding a new section 1848, "Payment for Physicians' Services". The new section contains three major elements: (1) Establishment of volume performance standard rates of increase for physician services expenditures; (2) replacement of the reasonable charge payment mechanism with a new fee schedule for physicians' services; and (3) replacement of the maximum actual allowable charge (MAAC), which constrains the total amounts that non-participating physicians can charge Medicare beneficiaries for covered services, with a new limiting charge.

On November 5, 1990, Congress enacted Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990, which contained several modifications and clarifications to the Public Law 101-239 provisions establishing the physician payment fee schedule. These modifications have been taken into account throughout this proposed rule. Public Law 101-508 also made a number of revisions to physician payment amounts for 1991, which will affect payment amounts under the fee schedule, given the budget neutrality requirement for 1992 and the transition rules. (Budget neutrality is explained more fully below in the discussion of the conversion factor (CF).)

This proposed rule is being issued in accordance with section 1848(b)(1) of the Act as added by section 6102 of Public Law 101-239, which requires that: "Before January 1 of each year beginning with 1992, the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas * * * for the year * * *." Section 1848 requires that the fee schedule include national uniform relative values for all physicians' services. The relative value of each service must be the sum of relative value units (RVUs) representing physician work, practice expenses net of malpractice expenses, and the cost of professional liability insurance (malpractice insurance). Nationally uniform relative values must be adjusted for each locality by a geographic adjustment factor (GAF). (Only one-fourth of the physician work relative value is subject to adjustment.) The CF (converting total RVUs into dollar payment amounts) is to

Therefore, we sent a survey questionnaire to all carriers to collect data on their current allowances for the items included in our list. From those carriers stating that they have a policy to pay separately for supplies, we propose to determine national average allowed charges for these supplies. We are also in the process of obtaining catalogs from national surgical supply companies to review information on list prices for the supplies for which we are considering allowing a separate payment. Based on our analysis of these data performed thus far, we expect to establish a fee schedule payment amount for selected supplies used for a facility-based procedure when it is performed in the physician's office. We are also considering limiting this proposed policy to only ASC procedures or to some other subset of procedures. We will continue to study this issue, and invite comments on the proposed policy.

We are especially interested in receiving comments on the issues of (1) our method of establishing fee schedule amounts for these office medical supplies, (2) the content of the list of office medical supplies for which we propose to provide separate payment, and (3) whether payment for such supplies, if made, should be limited to procedures on the ASC list or some other subset of procedures. Commenters who want additional office medical supplies to be placed on this list should provide a specific rationale for why the supply should not be considered to be routine practice expense and should provide supporting information on the cost of the office medical supply to physicians. Reference to items such as "trays" or "packs" should itemize the specific contents.

b. Services furnished incident to a physician's service. We propose in § 415.32(b) that services of nonphysicians that are covered as incident to a physician's service would be paid under the fee schedule as if the physician had furnished the service. This is a continuation of current practice under reasonable charge payment in which the physician bills reasonable charges for the services of staff that are incident to the care as if the physician had furnished the services personally. These services and items typically include the services of health professionals such as nurses or PAs who furnish a service under the direct supervision of a physician, for which the physician bills. For example, a registered nurse under the supervision of a physician may see a patient on the physician's behalf to administer an injection. The physician would bill for the injection as if the physician had administered it. Several CPT codes (for example, minimal established office visits and physical medicine codes) acknowledge these arrangements.

We request public comment on whether the policy of paying the same amount for the service whether furnished personally by a physician or by someone incident to a physician's service should continue. The salary of the nonphysician staff is a practice expense and the physician work in these services is arguably non-existent or at least something less than if the physician furnished the service directly. Because physicians bill for these services as if they furnished them personally, we do not know to what extent these services furnished by physician staff without a patient encounter are billed and paid as physician services. We are considering whether to require use of a modifier when these services are furnished by physician staff so that we can evaluate both their frequency and the amount of payments made for them.

c. Drugs. The program currently pays for drugs furnished in physician's offices that are not self-administrable under the "incident to" provision set forth in section 1861(s)(2) of the Act. For the most part, drugs paid for under the "incident to" benefit consist of drugs furnished by injection or by infusion. This includes chemotherapy agents. Generally, carriers base payment for the drug on the physician's estimated cost of the drug using one of the wholesale price guides such as the Red Book.

However, some carriers base payment on actual acquisition costs determined on the basis of carrier surveys.

We considered the following options for paying for drugs under the fee schedule:

Option l -- Establish a fee schedule payment amount for each drug.

Option 2 -- Bundle the payment for the drug into payment for the visit or consultation service.

Option 3 -- Make a separate payment for a drug and leave the pricing of the drug to each carrier.

Option 4 -- Make a separate payment for a drug but require a consistent method in pricing to be used by the carriers.

We believe that ultimately there should be a national fee schedule allowance for all "incident to" drugs. However, given the large number of different drugs and the myriad of dosage levels, we have decided that it is not practical for us to consider establishing a national drug fee schedule at this time. However, we will consider this issue in the future. Section 1848(j)(3) of the Act gives us the authority to specify that items and services be excluded from the fee schedule. Thus, we have decided to exclude the cost of drugs from the national fee schedule and to continue to pay for them under the current "reasonable charge" system. We believe, however, that there is a need for greater consistency in how drugs are paid for under the program and for this reason we have chosen Option 4. For purposes of payment for drugs furnished incident to a physician's service, the term "drug" includes those covered drugs and biologicals that cannot be self-administered. Also, we are proposing that we will instruct all carriers to base payment for drugs on 85 percent of the national average wholesale price of the drug (as published in the Red Book and similar price listings), but we welcome comments regarding the appropriate discount.

Medicare policy, since the beginning of the Medicare program, has been to base payment for "incident to" drugs on the estimated acquisition costs. However, based on studies by the Office of the Inspector General (OIG) ("Changes to the Medicaid Prescription Drug Program Could Save Millions" (ACN 06-40216) and "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program" (A-06-89-00037)) and other information, we believe that the Red Book and other wholesale price guides substantially overstate the true cost of drugs. The OIG reports indicate that pharmacies are getting an average discount of 15.9 percent off the published wholesale price. We have no reason to believe prices paid by physicians are any higher than pharmacies pay. Moreover, we are proposing for very high volume drugs that payment for the drug would be limited to the lower of the estimated acquisition cost for the drug as determined by us and specified in instructions to carriers or 85 percent of the national average wholesale price for the drug. The listing of the high volume drugs and payment limits for them will be included in the Medicare Carriers Manual.

We propose this payment policy for drugs that are incident to physician services under the authority of section 1842(b)(8) of the Act, which permits us to establish limits on charges based on inherent reasonableness. This provision of the law is implemented in regulations at § 405.502(g). The regulations permit us to establish a limit on the reasonable charge for an item or service if we

Like specialty level effects, these State level effects are generally consistent with those shown in earlier analyses. Payments in all States would be affected by the CF adjustments for the transition and behavioral effects, but the pattern of inter-State redistribution remains essentially unchanged.

There will also be redistributions of payments within States. Changes in payment levels could vary more widely if we compared smaller geographic areas than States, such as fee schedule areas. Variation at the fee schedule area level could be greater than at the State level, since the effects within States tend to offset one another. (For example, many States contain both urban and rural areas. Increases in rural areas may be offset by decreases in urban areas.)

e. Effects of separate payment for drugs. We have estimated the budgetary effects of our proposed policy for separate payment for certain drugs. As explained in section IV.A.5.c., carriers generally base payment for covered drugs on the physician's estimated cost of the drug using one of the wholesale price guides such as the Red Book, which is an annual pharmacists' reference published by the Medical Economics Company, Inc., Oradell, New Jersey. Under our proposed policy, carriers would be instructed to base payment for drugs on 85 percent of the national average wholesale price of the drug as published in the Red Book and similar price listings. Our policy would therefore reduce payments for drugs by approximately $10 million in FY 1992, $30 million in FY 1993, $30 million in FY 1994, $40 million in FY 1995, and $40 million in FY 1996.

2. Effects on Beneficiaries' Costs and Access to Services

Medicare beneficiaries incur out-of-pocket expenses in relation to their Medicare-covered services arising from (1) the monthly part B premium ($29.90 in 1991), (2) the annual deductible (increased from $75 in 1990 to $100 in 1991), (3) the 20 percent coinsurance, and (4) balance billing (that is, billing the beneficiary for an amount in excess of the Medicare allowed charge if the claim is not assigned). The implementation of the Medicare physician fee schedule and the limiting charge on balance billing as required by law and set forth in this proposed rule would have important effects on the amounts of beneficiary coinsurance and the amounts of balance billing permitted.

Concern about rising beneficiary out-of-pocket costs has led to an increasing emphasis over the past several years in encouraging physicians' Medicare participation (which requires accepting assignment for all cases), in increasing assignment rates, and limiting the amounts of balance billing. In fact, since Public Law 98-369 (the Deficit Reduction Act of 1984) established the participating physician program with its differential payment rates for participating and nonparticipating physicians, enrollment in the Medicare participating physician program has increased to 44.1 percent (April 1990 figure). Creation of the MAAC limits on balance billing (enacted as part of Public Law 99-509) gave physicians an additional incentive to participate. Participating physician charges represented approximately 63 percent of Medicare physician covered charges during CY 1990. At the same time, assignment rates have also increased steadily so that by CY 1990 the assignment rate based on total charges (physician and suppliers) had increased to 85.3 percent. With this increase in assigned claims and the MAAC limits that took effect in 1987, balance billing decreased from its CY 1986 high of $2.9 billion to a CY 1990 total of $2.2 billion, unadjusted for inflation or enrollment growth during this period.

Offsetting these declines in balance billing have been the recent increase in the deductible already mentioned, and continuing annual increases in the premium rate and increases in the amounts of coinsurance as the charges per service and volume and intensity of services have grown. Benefi-

Exhibit C

NEW YORK SUPREME COURT
COUNTY OF ALBANY

People of the State of New York Plaintiff v. Pharmacia Corp. Defendant	Index No. 904-03 RJI No.: 01-03-075848
People of the State of New York Plaintiff v. SmithKline Beecham Corporation, d/b/a GlaxoSmithKline Defendants	**NOTICE OF ENTRY** Hon. William E. McCarthy, J.S.C. Commercial Division Index No. 905-03 RJI No.: 01-03-076342
People of the State of New York Plaintiff v. Aventis Pharmaceuticals, Inc. Defendant	Index No. 1150-03 RJI No.: 01-03-076343

PLEASE TAKE NOTICE that the attached is a true copy of the Decision and Order issued by the Hon. William E. McCarthy on the 19th day of July, 2006 and entered and filed in the office of the Clerk of the Court on the 24th day of July, 2006.

Dated: Albany, New York
July 25, 2006

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STATE OF NEW YORK
SUPREME COURT COUNTY OF ALBANY

PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

Index No. 904-03
RJI No.: 01-03-075848

PHARMACIA CORPORATION,

Defendant.

PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

DECISION and ORDER

Index No. 905-03
RJI No.: 01-03-076342

SMITHKLINE BEECHAM, CORP., d/b/a
GLAXOSMITHKLINE,

Defendant.

PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

Index No. 1150-03
RJI No.: 01-03-076343

AVENTIS PHARMACEUTICALS, INC.,

Defendant.

(Supreme Court, Albany County, All Purpose Term)

APPEARANCES:

Hon. Eliot Spitzer
Attorney General of the State of New York
Attorney for Plaintiff

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McCarthy, J.:

The above-captioned actions have been consolidated for pre-trial purposes. Plaintiff has moved for an order compelling defendant Pharmacia Corp. to comply with discovery demands

relating to all prescription drugs sold by said defendant notwithstanding the fact that the complaint only specifically identified a small number of drugs. Defendant Pharmacia Corp. has moved for an order compelling the plaintiff to conduct a full and complete search for documents responsive to said defendant's demands in the possession of numerous different state agencies and the Legislature, compelling production of documents claimed to be privileged and documents covering the period from 1985 to the present. Defendant Aventis Pharmaceuticals has moved for similar relief.

The instant actions are brought pursuant to General Business Law § 349 and Executive Law § 63 (12) seeking to enjoin allegedly fraudulent and deceptive business practices, to obtain restitution to aggrieved consumers and state agencies which have allegedly overpaid for prescription drugs and to direct the payment of certain fines and penalties. As a means of background, pursuant to statute, a number of state agencies reimburse medical and prescription drug providers for some drugs dispensed to medicaid and medicare recipients, as well as certain elderly consumers covered by EPIC, a state sponsored prescription drug insurance plan, based upon the "average wholesale price" of the drugs as reported by a prescription drug price reporting service (*see* Social Services Law § 367-a [9] [b]; Elder Law § 250 [1] [a] and [b]). The statutes do not impose any restrictions or mandates with respect to how drug manufacturers are to report their "average wholesale prices" to the reporting service. Apparently, a longstanding industry practice has been to report some form of "list" price, rather than the actual discounted prices paid by providers to wholesalers and distributors. Indeed, the statutes on their face appear to indicate that the reported "average wholesale price" is not the actual price paid by providers. Both statutes provide that reimbursement shall be the lesser of the usual and customary charge to the general public or a significantly discounted "average wholesale price."

The State contends that, in recent years, a number of manufacturers, including defendants, have allegedly inflated their reported "average wholesale prices" well above the actual average prices paid for their drugs. This inflation, in turn, has the effect of increasing the reimbursements, and hence the profits, to providers who dispense such manufacturers' drugs. The differential is known as the "spread." A greater "spread" creates a significant incentive for providers to prescribe or dispense such drugs, thereby increasing the sales of such drugs. Indeed, the State alleges that Pharmacia Corp. actively marketed its drugs by promoting this "spread" and the consequent profits available to providers. The State contends that such increased prices have the effect of increasing the co-payments for consumers as well as increasing the costs to the State.

With respect to the instant motion practice, all three motions to compel discovery are entirely generic in that they fail to address any specific discovery demands. Indeed, defendant Pharmacia failed to submit a copy of the demand with which it seeks to compel compliance. The Court will follow this course charted by the parties.

Plaintiff seeks to compel production of information with respect to all drugs sold by defendant Pharmacia. Plaintiff contends that, because a prior motion to dismiss for failure to provide sufficient specificity in the complaint was denied, it is now the law of the case that all drugs sold by Pharmacia are covered by the litigation. Pharmacia contends that discovery should be limited to the drugs specifically identified in the complaint. The prior decision of Justice Benza, dated June 1, 2004 did not mention the issue of identifying specific drugs in upholding the complaint and, as such, has no impact on the outcome of the instant motion. Moreover, the complaint appears to list the specific drugs as examples with no intention to limit the claims to such drugs. Therefore, the scope of the instant action is not limited to the drugs specifically identified in the complaint.

However, plaintiff, as the party seeking to compel discovery, has the burden of establishing that the requested discovery seeks evidence which is material and relevant to the causes of action asserted in the complaint (*see Vyas v Campbell*, 4 AD3d 417, 418 [2d Dept 2004]; *Carp v Marcus*, 116 AD2d 854, 855 [3d Dept 1986]). The complaint on its face, as well as the relevant statutes, indicate that not all drugs are reimbursed based upon the reported "average wholesale price." Many drugs are subject to a "federal upper limit" and others may have lower retail prices. As such, plaintiff has failed to show that discovery with respect to all drugs sold by defendant Pharmacia is relevant. Accordingly, plaintiff's motion to compel production of information with respect to all such drugs shall be denied without prejudice to renew following service of a demand which properly narrows the scope of discovery in the event defendant Pharmacia fails to comply.

Defendants Pharmacia and Aventis seek to compel plaintiff to search numerous state agencies, as well as the Legislature, for information concerning how much such state bodies knew about the nature of the reported "average wholesale price" and when they acquired such knowledge. Plaintiff objects to the demands on the grounds that the information sought is irrelevant, that the state agencies and Legislature are not parties to this action and further that much of the information is privileged.

As indicated above, the defendants have the burden of showing that the requested evidence is material and relevant (*see Vyas*, 4 AD3d at 418; *Carp*, 116 AD2d at 855). Defendants contend that plaintiff alleges that the agencies and programs were defrauded into believing that the published "average wholesale prices" represented the actual prices paid by physicians and pharmacies for the various drugs. They also contend that the complaint alleges that the agencies were defrauded

because they tied reimbursement to the reported "average wholesale prices" based upon the understanding that these were the actual prices paid. The complaint against Pharmacia does not expressly contain any such allegations and Aventis has not submitted the complaint in the action against it.

Further, defendants also contend that, if they can prove that the state agencies knew that the reported "average wholesale prices" were not the actual prices paid, plaintiff's claims must fail. This argument fails. Reimbursement is based solely upon statutory formulae over which the agencies have no discretion or control. The agencies' understanding of what "average wholesale price" constituted is thus irrelevant.

Plaintiff contends that the "action turns on what the Legislature meant by "average wholesale price": Is it an estimate of actual acquisition cost, as plaintiff contends, or is it a 'sticker' or 'list' price that the manufacturer can set without reference to purchaser's actual acquisition cost, as defendant argue." (Plaintiff's memorandum of law at 4). However, plaintiff objects to providing discovery of evidence sought by defendants on the ground that it is not probative with respect to legislative intent.

Evidence with respect to an individual legislator's knowledge or interpretations of statutes, (*see Knight-Ridder Broadcasting, Inc. v Greenberg*, 70 NY2d 151, 158 [1987]), letters of individual legislators (*see Willett v Dugan*, 161 AD2d 900, 901 -902 [3d Dept 1990]) and reports which are not referred to in the bill jacket (*see Matter of Orens v Novello*, 99 NY2d 180, 188 [2002]) are not probative of the legislative intent. Rather, defendants must rely upon the public record in establishing legislative intent (*see e.g. Matter of Gropper v Tax Appeals Tribunal of State of New*

York, 9 AD3d 796, 798 [3d Dept 2004]). As such, the great bulk of the evidence sought by defendants is not relevant to the issue of legislative intent. In any event, plaintiff could recover upon a showing that defendants improperly manipulated the prior practice of reporting mildly inflated prices as "list" prices by substantially increasing the "spread" to increase sales even if the Legislature was aware of and accepted the mildly inflated pricing when it established the reimbursement formulae. Therefore, evidence that the Legislature and state agencies knew that the reported "average wholesale prices" were inaccurate and when they knew it is not relevant herein. This includes evidence related to such issue going back to 1985, as sought by defendants.

Plaintiff also contends that neither the Legislature nor the agencies are parties to the instant action and, as such, defendants must follow the procedures applicable to obtaining discovery from non-party witnesses. CPLR 3102 (f) provides "[i]n an action in which the state is properly a party, whether as plaintiff, defendant or otherwise, disclosure by the state shall be available as if the state were a private person." Thus, it has been held that a defendant in an action brought by the Attorney General pursuant to the General Business Law and the Executive Law to prevent fraudulent conduct is entitled to full discovery from the state (*see People v Katz*, 84 AD2d 381, 383 [1st Dept 1982]; *see also People v Bestline Prods.*, 41 NY2d 887, 888 [1977]). Therefore, discovery of evidence within the possession, custody or control of the Attorney General is discoverable. This certainly includes evidence relating to payments for the various drugs for which plaintiff seeks restitution which is in the possession of the affected agencies. However, as indicated above, it is unclear what drugs are actually the subject of this action. It would therefore be premature and wasteful to compel production of evidence with respect to drugs which may not be involved herein.

With respect to the motion to compel production of allegedly privileged documents, the privilege log served by plaintiff fails to provide sufficient information with respect to the documents to allow the Court to determine whether any privilege applies. An *in camera* inspection would therefore be required (*see Geary v Hunton & Williams*, 245 AD2d 936 [3d Dept 1997]). However, given the generic nature of the motions, the fact that many of the documents concerning which plaintiff has asserted various privileges are not relevant, and the fact that the scope of the action has not been defined, an *in camera* inspection would be premature at this time. Rather, the parties are directed to appear for a preliminary conference to establish a discovery schedule, which should include, among other things, a time frame to serve a bill of particulars to define the affected drugs and the amount of restitution claimed. The Court will schedule such conference by separate letter.

Accordingly, it is

ORDERED that the motions to compel discovery are hereby denied.

This memorandum shall constitute both the decision and the order of the Court. All papers, including this decision and order, are being returned to former counsel for plaintiff. The signing of this decision and order shall not constitute entry or filing under CPLR 2220. Counsel is not relieved from the applicable provisions of that section relating to filing, entry and notice of entry.

IT IS SO ORDERED!

Dated: JULY 19, 2006
Albany, New York

William E. McCarthy, J.S.C.

Papers Considered:

1. Notice of Motion dated June 29, 2005;
2. Affirmation of Carol Beyers, Esq. affirmed June 29, 2005, with Exhibits 1-12 annexed;
3. Exhibits 1-6 submitted by defendant Pharmacia;
4. Notice of Motion dated June 30, 2005;
5. Affidavit of Jason E. Baranski, Esq. sworn to June 29, 2005, with Exhibits A-L annexed;
6. Notice of Motion dated June 30, 2005;
7. Affirmation of Steven L. Saxl, Esq. affirmed June 30, 2005, with Exhibit A annexed;
8. Affirmation of Matthew Barbaro, Esq. affirmed May 12, 2006, with Exhibits A-E and G annexed;
9. Affidavit of Gregor N. MacMillan, Esq. sworn to July 13, 2005.

r/Madam:

ıke notice that the within is a copy of the

_____duly filed

d entered in the office of the Clerk of

_____ County, on the _____ day

_____, 2006.

ɔurs, etc.,

LIOT SPITZER,

torney General
torney for the Plaintiff
ıe Capitol
bany, NY 12224

SUPREME COURT OF THE STATE OF NEW YORK, COUNTY OF ALBANY

PEOPLE OF THE STATE OF NEW YORK

Plantiff,

–against–

PHARMACIA CORPORATION,

Defendant.

PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

SMITHKLINE BEECHAM, CORP., d/b/a GLAXOSMITHKLINE,

Defendant.

PEOPLE OF THE STATE OF NEW YORK,

Plantiff,

-against-

AVENTIS PHARMACEUTICALS, INC.,

Defendant.

DECISION and ORDER
Index No. 905-03
RJI No.: 01-03-076342

ELIOT SPITZER
Attorney General